

## REMARKS

### **I. Introduction**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Applicants request amendment of the title.

Claims 2 and 7 are requested to be canceled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Upon entry of this Amendment, claims 1, 3-6, and 8-19 will remain pending in the application.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

### **II. Response to Issues Raised by Examiner in Outstanding Office Action**

#### **a. Claim Rejections - 35 U.S.C. § 103**

Claims 1, 3-6 and 8-19 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Bell et al. (WO 97/38593) in view of The Merck Index (Monographs 5382, 5383, 6788, 9918 and 9932), Zawistowski et al. (WO 01/91587), Laughlin (US 5,470,839), Stedman's Medical Dictionary (22<sup>nd</sup> Edition, 1972; p. 1400), Mendy (US 4,407,821) and DeMichele (US 5,780,451).

The Office asserts that Applicant has not properly considered the references as a whole used together in order create the obviousness rejection. The office believes that a complete reading of the all of the references allegedly provides sufficient basis for the rejection and that an analysis of discrete combinations is inappropriate. Office Action, p. 9.

To establish a *prima facie* case of obviousness, there needs to be (1) some suggestion or motivation to modify the reference or to combine reference teachings, (2) a reasonable expectation of success, and (3) the prior art references, when combined, must teach or suggest all the limitations of the claimed invention. *See* MPEP §2143 (Aug. 2001). “Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant’s disclosure.” *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). Applicants respectfully assert that the examiner has not met his burden.

Analysis of the entirety of the references used by the Office would not lead a person of ordinary skill in the art to the current invention. Stedman’s and Merck are used by the Office to provide information known to one of skill in the art regarding the source and structure of the different acids or additives used in the invention. Office Action, dated April 27, 2005, pp. 8-15. Laughlin, Mendy, and DeMichele are used by the Office to provide information regarding the use of vitamins and additives to nutritional products. *Id.* at pp. 12-14. Zawistowski is used to provide information about the use of certain long chain fatty acids and their equivalents in food nutraceutical compositions. *Id.* at 11. Finally, Bell is used to disclose compositions with medium and long chain triglycerides from different sources. *Id.*, at pp. 8-15.

The Office continues to assert that “Bell and Zawistowski are directed to resolving the same problem of dietary and nutritional supplementation and each test its suitability for use in diabetic patients.” Office Action, p. 4.

Applicants note that Zawistowski excluded women with diabetes from their studies. See page 22, Example 2. In addition, Zawistowski is directed to a method of reducing weight gain and maintaining a healthy body weight. See page 4 of Zawistowski and claims.

While Bell is directed to the regulation of night time hypoglycemia in diabetics, the supplement bar helps to regulate the level of sugar in the blood. The invention in Bell differs from the subject matter of the current claims and Zawistowski, since Bell merely discloses a diabetic supplement bar containing a particular amount of simple carbohydrates for the treatment or prevention of nighttime hypoglycemia in a diabetic patient. By contrast, claim 1 of the present claim set relates to a completely different method, namely a method for

supplementing the diet of a subject with diabetes mellitus comprising administering to the subject medium-chain triglycerides or a composition comprising medium-chain triglycerides in an amount sufficient to regulate or normalize fat metabolism in the subject. This amount of the medium-chain triglycerides is defined as being 10-30%. Bell is completely silent with regards to this range of medium-chain triglycerides, let alone that this range is suitable for regulating and normalizing fat metabolism in a subject. On page 2 of Bell, lines 31 to 33, it is merely stated that the diabetic supplement bar should further include about 2-30% by weight lipid. In lines 33 and 34 it is stated that in a preferred embodiment the lipid source comprises a medium-chain triglyceride and a long chain triglyceride. In other words Bell does not disclose and does not suggest the method of claim 1 requiring an amount of 10-30% medium-chain triglycerides which are sufficient to regulate and normalize fat metabolism in a patient. In addition, Bell does not provide guidance with regards to the other aspects of claim 1 including the use of one monounsaturated fatty acid, linoleic acid,  $\alpha$ -linoleic acid; and eicosapentaen acid and/or docosahexaen acid as multiple unsaturated triglycerides.

Finally, the person skilled in the art had no incentive to combine the teaching of Bell with the teaching of, for example Zawistowski, since the subject matter of Zawistowski totally differs from the subject matter of Bell. As noted above, Bell relates to regulating the carbohydrate levels of patients with diabetes. Diabetes can be a debilitating disease to patients who cannot properly regulate their sugar levels. For these patients, Bell offers a bar to regulate nighttime hypoglycemia. However, for patients trying to affect other aspects of diabetes, such as fat metabolism, Bell is not a relevant reference. One would not be motivated to combine the teachings of Bell, which relate to sugar metabolism, with Zawistowski, which relates to the regulation of body weight, in order to solve an issue associated with the current application, regulation of fat metabolism.

Combination of the other references relating to vitamins and other additives do not remedy these deficiencies. Applicants request reconsideration and withdrawal of the current rejection.

**CONCLUSION**

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

It is acknowledged that the foregoing amendments are submitted after final rejection. However, because the amendments do not introduce new matter or raise new issues, and because the amendments either place the application in condition for allowance or at least in better condition for appeal, entry thereof by the Examiner is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant(s) hereby petition(s) for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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